Cal/OSHA Advisory Meeting on Airborne Infectious Diseases
November 5, 2004 1515 Clay St. Oakland CA

Chairs: Deborah Gold, Bob Nakamura

Attendees:
Lauri Alvarez, 3M Company
Bob Barish, Cal/OSHA
Chris Cahill, California Department of Health Services, L&C Program
Chester Choi, MD, California Medical Association
Mitch Cohen, Kaiser Permanente
Herbert W. Dunmeyer, BD Medical
Enid Eck, Kaiser Permanente
Sue Eisberg, Sutter Health
Rebecca Fagan, Queen of the Valley Hospital
Cindy Fine, Tenet SRRMC
Mike Gugino, California Department of Corrections
Marguerite Jackson, UCSD Schoold of Medicine
James Janis, AFN SEIU Local 535
Lily Kaneshige, Kaiser Permanente
Pat McCarthy AFN SEIU Local 535
Marian McDonald, RN, California APIC
Jennifer McNary, California Department of Health Services, EH&S
Kay McVay, California Nurses Association
Janet Macher, California Department of Health Services
John Mehring, Service Employees International Union
Mary Mendelsohn, CACC
Tom Mitchell, Occupational Safety and Health Standards Board
Mark Nicas, University of California, Berkeley, School of Public Health
Bebs Nonato, AFN SEIU Local 535
Mary Anne O'Leary, San Francisco Department of Public Health
Pamela Persaud, St. Joseph Health System
Zohreh Pierow, Santa Clara County
Sandra Prickitt, AOHP
Janice Prudhomme, California Department of Health Services, Occupational Health Branch
Roger Richter, California Healthcare Association
Sonia Rosenberger, University of California Berkeley
Kenneth Smith, Department of Health Services, Richmond Lab
Steve C. Smith, Cal/OSHA
Laura P. Vo, City of Sacramento
Vicky Wells, San Francisco Department of Public Health
Paul White, Sutter Health Risk Services

Summary of Key Points

1. Initial source control measures, based on symptoms are important. These should include cough etiquette, early identification of potential cases, and isolation. Control measures should be changed as the diagnosis becomes more defined. Currently cough etiquette guidelines are not fully implemented in most institutions. There should be an "applications" section of the standard to address which portions of the standard address which types of operations.

2. Most participants believed that the diseases to be included and control measures should follow the CDC guidelines for infection control in health care and related documents. There will be a separate meeting to consider application in laboratory settings.
3. The exposure control plan (ECP) should allow/require facilities to define appropriate control measures for various settings. The ECP should address surge capacity as well as normal operations.
4. It is appropriate for the regulation to incorporate specifications for ventilation systems, airborne isolation rooms, etc. that are published by various sources including the CDC and the Office of Statewide Health Planning and Development (OSHPD). Ambulatory care and community based facilities are not generally able to provide this level of engineering controls so arrangements with hospitals and similar facilities should be preplanned.
5. Participants discussed whether N95 respirators are adequate for prevention of transmission of infectious agents, and whether quantitative risk assessment can or should be done. There was discussion about the use of Powered Air Purifying Respirators (PAPRs). Participants also discussed whether alternative procedures to annual fit-testing would provide adequate protection.

Bob Nakamura opened the meeting at 9:35, welcoming and thanking the attendees for coming to the meeting. He introduced Tom Mitchell, Deborah Gold, Steve Smith and Bob Barish. He then asked the attendees to introduce themselves, and their affiliation.

B. Nakamura explained that this is the second advisory meeting to consider a proposed airborne infectious disease control standard that the Division could then take to the California Occupational Safety and Health Standards Board (Standards Board). Since most attendees were aware of most of the issues, a very brief summary of events was given. He said that this process was prompted by the Federal OSHA decision to drop the proposed TB standard which put the use of respiratory protection under the general industry Respiratory Protection Standard. This action required the Standards Board to take an equivalent action, and as a result the California respiratory protection standard now applies to TB. Two major effects of this action are to require annual fit testing and the use of the questionnaire in Section 5144 Appendix C for medical evaluation of a user's fitness to use a respirator. When the change was adopted by the Standards Board in June, many affected parties requested that the Division have an advisory meeting to discuss any problems created by this action in the context of a general airborne infectious disease standard. The first meeting was held in July.

At the July meeting a draft standard that had been sent out earlier, was discussed. There was a general consensus to use an approach that started with source control and applying procedures like the CDC cough etiquette. The group also supported having an Exposure Control Plan, similar to Bloodborne pathogens which would include exposure assessment, control measures, training and employee involvement, and medical surveillance. At this meeting, some people said that they were having problems implementing annual fit-testing by the October 18, effective date. Some people were also having a problem due to a high number of examinations resulting from the Appendix C medical evaluations. This prompted the Division to propose an emergency regulation to the Standards Board that would phase in the deadline for annual fit-testing (Oct. 18 for high risk and January 18 for the rest) and grandfather medical evaluations that had been conducted for respirator use prior to October 18th.

Scope

D. Gold noted that attendees were asked to send in any comments or revisions regarding the definitions section but none were received. She then introduced the scope section of the standard. Marian McDonald asked about the definitions of engineering controls such as the number of air changes required for negative pressure rooms. D. Gold said that the specifications for isolation rooms were in the engineering control section. Chester Choi asked if this standard would apply to all doctors offices. D. Gold responded that it would be depend on the type of exposure and practice, for example it would probably not apply to a

dermatologist's office, but that portions of it would apply where there is first contact with people who have respiratory diseases. The definition of occupational exposure would be used to make this determination, and if it applies, the employer will have to do something to provide employee protection. What would be expected in a doctor's office, such as symptom recognition, would be different from what's expected in a hospital. C. Choi said that this needs some thought.

Mitch Cohen noted that there could be a problem in communities where there is a low TB prevalence. The Centers for Disease Control (CDC) has incidence rate and risk assessment included in their recommendations. D. Gold noted that this standard goes beyond TB to other diseases. So, what we are looking at, based on the first meeting and other comments presented to the Division, is broadly applying lower cost source control measures, like cough etiquette. Also health care employers need to be alert for new or emergent diseases, identify potential cases by symptoms, and train employees on what to do. Kaiser is much different from a free standing clinic but both would train first contact people. This proposal is not intended to require isolation rooms in every clinic. Marguerite Jackson said it was good idea to refer to current CDC guidelines. She said that her committee expects the HICPAC [Hospital Infection Control Practices Advisory Committee] guideline to be issued in spring of next year, and they are on draft 9 now. The lead of the TB group revising the 1994 CDC guideline expects to have the new version out next year also, and it will cover respiratory protection. D. Gold mentioned that the CDC has already put out a recommendation on cough etiquette.

M. McDonald commented that she supports the OSHA reliance on the current CDC guidelines. D. Gold noted that it is good when Federal OSHA makes that kind of broad reference, because it allows the California standard to do that. Generally, state rulemaking requirements limit Cal/OSHA standards to referencing specific documents, including the specific version. Enid Eck said there needs to be a way to incorporate underlying principles, for example, focus on source containment as the basis for risk assessment. A front office would need to know what symptoms to look for. There are ongoing risk assessments by the local county health departments; using these might clarify interpretations. There should be a list of diseases, such as flu, anthrax, small pox, SARS, etc. M. Jackson suggested the use of the list that had been published as an appendix to the CDC document on isolation procedures that had been noticed in the Federal Register. She added that this standard applies to more than TB, and there should be clarification to distinguish between diseases for which airborne isolation is recommended and diseases for which droplet precautions are recommended. Cindy Fine asked how diseases for which droplet precautions are recommended fit into this standard. We need to identify the important pathogens, and which diseases to focus on. D. Gold responded that the intent is rely on the CDC list. The underlying concept is source control, and this includes diseases spread by droplet and airborne transmission. C. Fine noted that some diseases don't present with easily identifiable symptoms.

Janet Macher noted that for laboratory exposures, the scope would have to encompass almost all diseases because there are procedures that can generate aerosols with infectious material. D. Gold agreed and said that there will be a separate meeting to address laboratory issues, There might be an approach similar to the biosafety cabinet standard, in referencing the BMBL [CDC publication Biosafety in Microbiological and Biomedical Laboratories]. The controls and the exposures are different for labs, for example there may not be the concerns regarding coughing patients. There could either be a separate standard or section in this one.

D. Gold asked if the group agreed with E. Eck's approach of requiring some initial control measures based on symptoms, and then moving to more specific controls as the case becomes more defined. Marian McDonald agreed that source control is important and emphasized distinguishing between droplet and airborne as more information becomes available.

Mary Mendelsohn asked whether the numbering in the draft proposal "Note to (a)(2)" was a typo, and D. Gold said it was, it should be (b)(2). D. Gold added that the purpose of the note is to distinguish between on-

scene first response to a biological release whether due to terrorism or some other event, and the "first receivers" who are providing off-site treatment, although there can be some overlap of exposure. OSHA has issued a first receiver document, and that has some overlap with hazwoper. OSHA recommends that people involved in off-site operations as first receivers receive 8 hours of training and training in the specific PPE and decontamination. This concept is still somewhat in flux. E. Eck asked whether (b)(2) would apply to the emergency department of a hospital. D. Gold said that it would, if they were designated to receive people in the event of a biological release. E. Eck said that (b)(2) should state that it applies to emergency departments, and D. Gold said that should be in the definition of "first receiver." M. Jackson suggested adding a definition of first responder for clarification, and several people agreed that it was important to clarify first responders vs. first receivers. Chris Cahill asked if the release considered here in the definition of first receiver was limited to infection concerns and biologicals, or whether it included chemical releases. D. Gold responded that for the purposes of this standard it would only be airborne infection hazards.

M. McDonald said that the regulation needs to address requirements for ambulatory care areas, where there are no negative pressure rooms or other engineering controls. For example, what should a facility do when patients are wearing mask? Does a masked patient mean health care workers need to be wearing respirators? D. Gold asked whether people thought there should be an "Applications" section which identifies what control measures and requirement apply to which operations. There was general agreement. Pamela Persaud said it should address what to do in patient waiting areas. If a lot of people came in coughing, there wouldn't be enough isolation rooms, because there is no space. D. Gold said that the approach in the draft standard is to use the exposure control plan to set a procedure for dealing with situations, with specific control measures. She said that specific control measures would be addressed later in the meeting, and that the current draft requires moving a patient requiring airborne infection isolation to a facility with a negative pressure room within 5 hours if the initial facility doesn't have them. M. McDonald said that there are isolation rooms in patient care units, but not in imaging departments, so should they have N95s? If the person who transports the patient is using a respirator, is that information that the imaging department should also use respirators? Kay McVay added she is very concerned about homeless shelters and other places that are not health care facilities. If you can't get them to come to a meeting, how will you get them to take this on?

Mike Gugino asked what a correctional facility is supposed to do if you can't immediately transfer someone out to a medical facility. D. Gold asked if there are contracts or other pre-arrangements with hospitals? Roger Richter responded that there are fewer such arrangements in general, and the distance to the remaining hospitals has therefore increased. D. Gold asked M. Gugino how they handle TB outbreaks. M. Gugino responded that at Solano they quarantined everyone, and took some to the hospital. D. Gold said that it is hard to get the other types of employers to come to a meeting that is mainly about hospitals and other larger heath care facilities. She said that Cal/OSHA would probably have to hold subcommittee meetings to reach home health, homeless shelters, and other environments. The intent of the current draft is that the employer needs to identify clearly what they can do, and plan for what they will do, if they need to go outside their facility. There are additional problems for home health, because the patient may not have TB but it may be present in the home, or there may be some other disease.

Ms. McDonald noted that an unintended consequence in corrections might be that healthcare sites receive lots of coughing inmates. She asked if corrections facilities implement any controls for diseases requiring droplet precautions, and C. Cahill said that they try. D. Gold said that the facility needs to have procedures for disease outbreaks, but it should assess the patient and determine if they meet the suspect case definition prior to transport. Source control and other initial measures should be taken at the institution. Chris Cahill said that the purpose of the document is to try to identify cases and then take appropriate actions, particularly as the case becomes confirmed. But how do you screen in a homeless shelter? At some point, you need medical assessment. E. Eck said that's another reason to clarify things in an applications section. The exposure control plan should tell people how to do the initial identification. Not every cough reflects a disease. The standard should lay out and describe the principles of identification and control.

C. Cahill suggested changing the title of subsection(c) to add "airborne" or "respiratory," to clarify that the plan does not apply to all infectious diseases. C. Fine asked about the language in (c) regarding tasks. She said that tasks should be listed or specified. D. Gold said that the language in subsection (c)(1)(B)2. is meant to require that there be specified protocols for high risk procedures such as bronchoscopy. C. Fine said that with SARS, protections were incorporated haphazardly or even completely omitted depending on the facility. D. Gold said that is the reason for this provision, to add specific, required actions to take for outbreaks. There may be differences for isolation and treatment, and engineering controls. This includes developing procedures for situations that are not routine. E. Eck added that BBP has categories of tasks, and that could be added here. You have to think beyond TB. You need to go from initial generic precautions to more specific control measures for significant infectious diseases, and the definitions need to stay open-ended. This should provide confidence for everyone involved that they are prepared and have what they need for outbreaks. D. Gold noted that the idea of the exposure control plan is to identify what are routine controls, and then to be able go beyond it.

Work Practices and Engineering Controls

Bob Nakamura started the discussion on work practices and engineering controls. He explained that the draft includes an initial source control approach. He asked what facilities are currently doing, and if it is general practice for facilities to implement the cough etiquette. C. Cahill said that she has been to eight hospitals in the last eight weeks. There are signs for cough etiquette procedures especially in emergency departments, especially for patients to put on a mask. But the rules are relaxed when there is no crisis. The person in charge of triage is usually the one that would enforce it, and they aren't doing it. E. Eck said that's why it's important to put it in the regulation, so that it makes it routine, and applicable to all patients for whom it is indicated. That way you don't have to negotiate with them. When it's a seasonal practice, people get laid back, and you end up arguing with patients. M. Mendelsohn noted that the seasonal approach is actually reinforced in part by DHS and other public health agencies that issue notices with seasonal alerts for flu, or a an alert about travel during SARS. The cough etiquette approach does need to be standardized year round. John Mehring asked if it is required by DHS. C. Cahill said that DHS regulations can be interpreted that way, but they are do not specifically require it. It is based on the surveyor's judgment, there is nothing in writing from DHS. B. Nakamura asked if it is required by JCAHO. C. Cahill said that JCAHO also has nothing specific, although it mentions communicable diseases. E. Eck said you don't get cited for not doing it. M. McDonald said there are two pieces, maintaining supplies and enforcement of behavior. You need to specify an accountable individual by department to do this. It could be the ECP administrator. M. Jackson said that when HICPAC and CDC come out with their guidelines, infection control facilities will review them with regard to putting them into practice. It is good for this standard to reinforce that in the ECP. C. Cahill said it is important to educate the patient, for example you can put it on the TV in the ED. B. Nakamura asked if DHS requires patient outreach. C. Cahill said they require patient education. B. Nakamura said Cal/OSHA may not be able to require patient education E. Eck suggested putting it into the exposure control plan – the employer is responsible for assuring supplies for respiratory etiquette, patient outreach, and providing information. P. Persaud said that their two hospitals hand out patient information. E. Eck said that APIC and CDC have flyers, materials and posters.

K. McVay said that you need to educate nurses and other health care workers to raise their awareness. Kaiser puts out pamphlets. J. Mehring asked what are the best practices around cough etiquette? He would like a better picture of what's going on now. How available are masks? Where are they kept? Are security people involved in implementing the program? He thinks that's true in some institutions, and that's probably not good practice. The use of cough etiquette shouldn't be seen as a message directed against an individual. Health care providers need back up from their supervisors, there needs to be adequate signage and procedures for masking. How can patients wash their hands in the ED? Are their waterless systems?

C. Fine said that subsection (d)(4) doesn't apply to diseases requiring only droplet precautions, and subsection (d)(3) is not specific enough. She has signs everywhere. She has Purel. She finds that people don't replace the Kleenex. M. McDonald agreed that implementation is often spotty. B. Nakamura summarized that people were saying that implementation of cough etiquette procedures is spotty, and that a standard may help to make it uniform.

Jim Janus introduced himself as a registered nurse from Kaiser who converted and developed tuberculosis while working in an ICU. His skin test had been negative for 30 years. He developed acute disease, and the TB was discovered through skin test. Patients are transferred from the ED to the ICU. The patient may have been suspected of TB, but other health care workers along the chain are not informed. The patient wasn't his patient. There was a breakdown in communication between the ED and the ICU. D. Gold asked if the standard should have a communication requirement regarding suspect cases. Bebs Nonato said that the standard should require communication regarding patients and the training of managers and staff, including staff in other units. For example a TB patient could be on a cardiology unit if they have open heart surgery. B. Nakamura asked if there would be a confidentiality issue. The group responded that there would not be a confidentiality problem within a health care institution. K. McVay said that there may be a note put on the computer that they are sending the patient up, but there is no communication between people. If you put down that the patient has "pneumonia", then the staff won't mask them. Communications are difficult between the busy emergency room and the busy ICU. B. Nakamura suggested putting a requirement in the exposure control plan section. S. Prickett suggested that Cal/OSHA develop a sample ECP, and S. Smith said that might be referred to the Cal/OSHA Consultation Service. M. Jackson said it was common for a TB diagnosis to be made after death. This emphasizes the need for good environmental controls in the ICU, even if not in an airborne infection isolation room. There should be good air exchange, and this may be something OSHA can help with. A pneumonia diagnosis does occasionally turn out to be TB.

M. Mendelsohn said that the draft addresses all of this. Each facility will need to write specifics into their plan. You need to plan on communications breakdowns. You need source control and universal precautions. If a patient has respiratory symptoms, someone should be wearing a mask. M. Gugino asked if a patient wearing a mask wouldn't identify the patient as being a suspect case. E. Eck said that sometimes you can't mask the patient. M. McDonald said that you can't mask a patient if they are intubated, and also some patients can't breathe through a mask. E. Eck said that she had gotten tuberculosis that way while in nursing school. She took care of a patient for six weeks who had "pneumonia." She got TB, and was on INH for a year. Practices can change, you need to change the way institutions operate. You need to move on parallel tracks with universal precautions for respiratory disease, and provide training. This is similar to instituting standard precautions, you needed to reinforce precautions with education. D. Gold asked if she thought an educational appendix would help. E. Eck said that it should focus on the universality of precautions for respiratory disease rather than on specific diagnosis.

M. Jackson noted that diseases requiring airborne infection isolation had been left out of subsection (d)(2). M. Mendelsohn noted that (d)(2) should use the term hand hygiene rather than hand washing. J. Mehring asked why employees should not be washing. E. Eck said that her facilities provide a choice, either washing with water or using alcohol based products. M. McDonald stated that there are better results with alcohol.

B. Nakamura then asked for specific comments on sections (d)(3) and (d)(4). C. Fine asked why the term "area" was used in (d)(4)(B). She asked what a negative pressure area was. P. Persaud said that the OSHA first receiver document refers to temporary facilities, such as tents. D. Gold said that one use of the term "area" includes surge capacity. C. Fine said that SARS units had been rooms. C. Cahill said she thought the standard should separate requirements for patient rooms from surge capacity, in terms of ventilation requirements. B. Nakamura asked what dictates whether an older facility has isolation rooms. K. Smith said that it is important that air flow be from non-infected areas to infected areas, and that at all times air should come from the nurses' station. B. Nakamura asked whether every hospital has isolation rooms. M. McDonald

said no. B. Nakamura asked if they would transport the patient to another facility. C. Cahill said that most hospitals will have portable HEPA units. M. McDonald said, regarding subsection (d)(6), that OSHPD [Office of Statewide Health Planning and Development] regulations grandfather in negative pressure rooms with 6 air changes per hour (ACH). R. Richter said that he would talk with N. Kellman at OSHPD regarding some of these questions.

E. Eck said that the exposure control plan should differentiate between routine and surge operations. C. Fine said that she would like to separate room from area. M. McDonald suggested leaving "room" in (d)(6) and addressing surge in the exposure control plan. D. Gold asked if there were other areas in a fixed facility that are under negative pressure that would not be considered a room. E. Eck said that there are booths, such as those for pentamidine administration. She suggested keeping the word "area," giving an example such as "booth," and putting surge capacity into the Exposure Control Plan. C. Choi asked if 12 ACH can be accomplished with HEPA filters to supplement existing ventilation system. D. Gold said that OSHPD already grandfathers those situations in in Title 24, Section 417. Requirements of subsection (d)(6) are only for those facilities not included in the OSHPD regulations. M. Cohen suggested clarifying that in the proposal. C. Fine said that (d)(6)(F) is confusing in situations where the window is part of the ventilation system. M. Gugino said that their patients live in their institutions. Their employees are concerned regarding how long to maintain precautions for a patient. C. Fine said that the CDC addresses the issue of how long precautions must be continued for different diseases. M. McDonald said that negative pressure rooms and other control measures only apply to diseases requiring airborne isolation, and those diseases are pretty rare. You can use HEPA filters for diseases requiring droplet precautions. K. Smith asked which diseases are defined as droplet precautions, and D. Gold responded that the proposal is to go with the CDC table.

C. Cahill suggested separating airborne infection isolation from alternative source control measures, like portable HEPA filters. The 1994 CDC tuberculosis control guidelines also permit you to make a room negative pressure using a HEPA unit vented to the outside. E. Eck asked it this standard would be prescriptive on changing filters and maintenance. The exposure control plan should address the manufacturer's maintenance recommendations for auxiliary equipment. M. Cohen asked about the requirement to qualitatively demonstrate negative pressure. Their facilities have automatic systems to detect the pressure differential, do they really need to do an additional smoke test? J. McNary said that it's important to ensure that magnihelics and other equipment used to test negative pressure be calibrated. M. McDonald and C. Cahill said there is some language on alarms in the new draft AIA [American Institute of Architects] guidelines. M. Jackson questioned the five-hour time-frame for transferring a patient to an isolation room.

Medical Surveillance, Vaccination, and Treatment

D. Gold introduced the discussion of medical surveillance. At the previous meeting, there was strong support for requiring employers to provide vaccinations for vaccine preventable diseases, including a requirement that employers obtain a declination from employees who chose not to be vaccinated. In later comments to the Division, people raised concerns regarding the implementation of a declination for the annual flu vaccine. So this proposal contains one alternative method of documentation, which is contained in the exception to (g)(4) permitting the employer to essentially rely on a signed training log. C. Fine asked if everyone uses a signed training log. P. Persaud said that that procedure would be too hard to implement, and they still would not get everyone. M. Mendelsohn said that they send out flyers and mailers, but they don't do a training meeting. E. Eck said the driving idea behind this proposed requirement is that there is enough research, including research supported by the SEIU, to show the importance of vaccine. Frank Myers has found that the way the declination is presented makes a difference. When vaccination is presented in terms of patient as well as employee safety, health care workers were more inclined to get the vaccination. M. McDonald asked if there couldn't be a requirement to get 90% compliance with the vaccine or declination, because it is impossible to get everyone. M. Jackson asked if that would be okay if you documented the solicitation. They place notices

with paychecks, and post signs in elevators and hallways. D. Gold said the question would probably come down to "effective procedures." A participant said that if the vaccination were made a condition of employment, then a declination wouldn't be necessary. D. Gold said that except for the respirator medical evaluation, Cal/OSHA typically requires employers to provide medical surveillance, but does not force employees to participate. She said she could check with others in the agency. M. Cohen said he thought it was okay as it is.

C. Fine asked if the requirement in (g)(1) that the employer offer an alternative medical provider for post-exposure evaluations is necessary. D. Gold said that the BBP standard includes a similar requirement. In practice, employers have made reciprocal arrangements with another facility. C. Fine said that for BBP it had to do with HIV confidentiality. D. Gold responded that the expectation of confidentiality is important to effective evaluation and treatment. Specifically for TB, an exposure involves increased risk for immuno-compromised employees, and the employee needs to feel free to share his or her concerns with the health care provider, without fearing that the information will get back to the employer. Whether the confidentiality issue is real or perceived, it can keep employees from getting treatment. P. Persaud said that at St. Josephs when there is a BBP exposure incident, a workers compensation claim is made, and the employer controls the information. D. Gold said that under the BBP standard, the employer has to designate an alternate provider. They don't have to let the employee choose the provider, they just have to have an alternate that is outside their system. The employer further has to arrange to protect employee confidentiality, and inform the doctor that only limited, specified information is to be conveyed to the employer. This information is contained in the standard as the contents of the "written opinion."

C. Fine noted that for some types of vaccines it would not be possible to get a vaccination within 10 days. M. Mendelsohn asked about availability problems. D. Gold said that issue is addressed in the exception to subsection (g)(4)(B). E. Eck said that referring to the wording of providing the vaccine within 10 days of recommendation is a problem, because the vaccine is not available for flu for several months after the flu strain is identified. D. Gold said that they would look at that wording again. C. Cahill said that the wording of (g)(4)(C) should say CDHS recommends, rather than require, because CDHS only issues recommendations. D. Gold noted that the use of the term TB Test in subsection (g) is to permit the use of Quantiferon or any other test that might be approved as an alternate to PPD. There is also language in the definition section.

RESPIRATORS

D. Gold introduced the section on respiratory protection, including selection, medical evaluation and fit-testing. In terms of selection, some people have questioned whether N95s provide sufficient protection against TB in clinical settings, and there has also been discussion about appropriate respirators for other diseases and for catastrophic events. D. Gold reported that she had contacted John Schaefer at Johns Hopkins about their respirator program. He explained that in the 1990s, Region 2 of OSHA was recommending elastomeric facepiece respirators with HEPA filers for TB. After investigation, Johns Hopkins determined that they would use Powered Air Purifying Respirators (PAPRs) instead of standard air purifying respirators. These were well accepted by users. For entrance into negative pressure rooms, they use a 3M loose-fitting facepiece that looks like a face shield. Each employee has their own facepiece. They determined that the most people who would need to be at a bedside in an isolation room at one time was five, so they have five PAPR motor units with batteries in the ante room or other support area. The health and safety staff determined they would need 600, but the administration decided to buy 1000 of the PAPR units. For an unknown event, SARS, or anthrax, they would use the more protective hood with a neck closure. They have also bought N95s, which will be for voluntary use only. The N95s would be used if there was a disease outbreak, such as smallpox. In that case the hospital would be divided in two, between infected and non-infected. The N95s would be available in the non-infected area for voluntary use. Although the decision was

made because the PAPR has a higher protection factor, they determined that when you include the cost of administration of the respirator program using N95 filtering facepiece respirators, the PAPRs are very cost-effective. There was good acceptance by nurses and doctors, including during procedures such as bronchoscopies, and they don't have to do fit-testing.

E. Eck asked if there were exposures shown as conversions at Johns Hopkins. If the epidemiology shows no exposure, then you don't know if the PAPRs reduced the risks. In most cases, the exposure to TB occurs before it is recognized, and respirators won't help. You need source containment. D. Gold noted that it would be good to have data from the facilities at the meeting on their own use of respirators, infection rates, and the circumstances surrounding conversions. C. Choi asked if that information was available from local health agencies, and people indicated that TB conversions are not reported. M. Nicas added that the statement from APIC said that they found conversion rates in hospitals that were the same as the community rates, and he would like to see the actual data they were using. He said that local health departments do not track conversion rates. D. Gold asked participants to provide data on conversion rates and the circumstances; this data would help in assessing how to control exposures. M. McDonald said that Frank Myers polled a number of hospitals and had some data. R. Richter said he thought that was in the letter that had been sent to the Standards Board.

C. Fine said it was one thing to use a PAPR for TB, but she questioned using the PAPR hood for SARS, since it would need to be decontaminated before re-use. She said that in Toronto, they used N95s for SARS, with a full suit, for standard care. They used PAPRs for SARS code blues. D. Gold said that Johns Hopkins had indicated that they were planning to use the gathered hoods for SARS, and she will request more information on that. J. McNary said that there was a report that in Toronto they used PAPRs for SARS. J. McNary said that the Emerging Infectious Diseases group is using PAPRs. E. Eck asked what the TB prevalence is in Baltimore and at Johns Hopkins. This information is necessary to know the full context of their decision. Lauri Alvarez said that instead of disinfection, some places were throwing the hoods away. C. Fine noted that the hoods cost $15 each. E. Eck asked if there were patient complaints about the PAPRs at Johns Hopkins. D. Gold responded that John Shaefer had indicated there was good acceptance of the faceshield type respirators by staff and patients. With the full face shield, you can see the user's face and there are no obstructions to their vision. M. McDonald asked if you can use a stethoscope with a PAPR. P. Persaud said that you can. S. Prickett said that some people liked the faceshield types a lot, since there was no obstruction. M. McDonald asked if a medical evaluation is required for the hood. D. Gold responded that it is, but that medical evaluations are not required to be repeated annually.

D. Gold continued that there is also an issue of whether an N95 respirator is adequate protection. Johns Hopkins decided it wasn't good enough. Some people have suggested using a higher level of respirator, at least for certain procedures. Should there be a risk assessment in the respirator selection. K. Smith noted that NIOSH has a selection guide. M. Nicas said that the term "adequate" is ambiguous. It becomes a risk assessment, in the end. But what is an acceptable risk is it 1/100, 1/1000, or 1/10000 annual risk? Agencies have not wanted to deal with the issue of risk, and use the expert opinion approach. But there is no estimate of risk, so you cannot make an assessment. Cal/OSHA should do the risk estimate and assessment. By analogy with the benzene standard court decision (for the federal OSHA standard) an increased risk of 1/1000 excess cancer cases was acceptable. You could make some estimate based on an acceptable level of cases, and the percentage of infections that develop to disease. But with TB, the cough frequency and the respirable aerosolized organism's viability in the sputum would have to be determined to calculate a risk level. These factors are uncertain but you could state the basis for your assumptions, and the framework would be completely transparent for review. This approach allows an informed choice for the employee.

C. Choi asked if the employee can decline to use a respirator, and was told that they cannot. E. Eck asked what the 1/1000 would be in this case and what factors it would be based on. M. Nicas said it would be based on the duration of exposure per patient, and how many patients would have TB. E. Eck said that any

decision should be based on evidence and data, not only on theoretical risk, but on what the epidemiology shows. Kaiser had places with no TB patient admitted for 2 years. It may make sense to have PAPRs in Baltimore, but maybe not in California. For the 1/1000 risk level, how many patients are you estimating, and in what time frame? M. Nicas said that you could use the typical number of contact hours for nursing staff with a TB patient, if that is tracked. Epidemiological studies often classify exposure by whether a person worked on a certain ward, but do not contain a detailed exposure assessment. E. Eck said that there might be a way to do that. But generally, the exposures occur prior to the TB diagnosis. Then they do a contact investigation, which is a thorough analysis of who was exposed to the TB patient. M. Nicas asked if the duration of exposure, such as the time in a room with the patient is recorded. E. Eck said it may be. That would be extremely difficult to track. M. McDonald said that most infection control practitioners have done an investigation on a TB conversion. Often you don't find a strong relationship to an exposure. D. Gold said it is hard to come up with exact numbers and risk assessments, but it is important to get as much data as we can into this process. There is also a need to get data that will allow us to show equivalence between different regulatory frameworks. M. Nicas' approach would help with all this. E. Eck said she would try to look at the available data and find out exposure times, etc. M. McDonald agreed that there should be some existing data, especially for exposures to TB without respirators. C. Choi said that we should get local and national data; many of the variables are unknown. You can't do a good evaluation of biological systems with just mathematical models.

J. McNary said the risk assessment should be done by Cal/OSHA, not by individual facilities. E. Eck said all data should be standardized and then provided to the Division. M. Nicas added that a retrospective study would investigate conversions. Cal/OSHA should also develop an approach for analysis. Federal OSHA used a method. It is difficult to model a system, but conceptually not that difficult. Need to characterize the air space around the patient, establish respiratory rates, emission rates, dispersion of particles, deposition fraction and size range, and establish an infectious dose, which may vary based on differences in susceptibility. Animal data shows that one bacillus is an infectious dose. TB probably has the most real data. C. Choi responded that there is variability in the infectivity of different strains, and there is also variability in host resistance. People live with TB patients and don't get infected. It is a difficult area to predict. M. Nicas said that is true but what else can you do? You could look at several orders of magnitude for infectivity and not determine what it applies to. D. Gold said that people with data should send it to her and Bob Nakamura. We need to share the data and other relevant information so that it can be put together for the next meeting. We need as good a basis for a proposed standard as possible. M. Jackson said that she hopes whatever comes out is shared. She hopes that there will be data at the upcoming CDC meeting on November 30, including risk assessment. The likelihood of a TB case is rare. Right now, it seems that the cost of preventing one TB death is over seven million dollars.

M. Jackson said that there is a concern, regardless of the type of respirator, about the nature and number of questions in appendix C that are not all necessary for the use of infrequently worn respirators. D. Gold said that for the current rulemaking, grandfathering in existing medical evaluations prior to October 18, 2004, the idea was that medical professionals evaluating this respirator use relied only a some of the questions, not on all of Appendix C. If California is going to propose an alternate medical questionnaire, we will need to have medical professionals evaluate and support an equivalent questionnaire content. We will also need to evaluate the physiological burden of an N95. She asked if this is worth the effort, and there was a general response that it was. K. Smith noted that some papers have shown that there is a big difference between N95s in their ability to fit people. Some fit very few people, some fit almost everyone. M. Gugino noted that the California Correction Peace Officers Association wants less medical evaluations, and in the Department of Corrections they only do an initial medical evaluation.

Fit-testing

B. Nakamura introduced the discussion about fit-testing requirements. He said that the draft circulated for this meeting contained a provision similar to the proposed federal TB standard. [OSHA has discontinued this rulemaking effort.] The draft for discussion today would permit an alternative for annual fit-tests, which is a face-to-face evaluation of the employee's ability to use the respirator. However, it requires an initial fit-test and a fit-test at least every two years. M. Jackson said that she supports the face to face evaluation including a user fit-check, and linking it to the TB test requirement, which requires a physical encounter with a person. The TB test generally includes a symptom evaluation as well. P. Persaud said that they did initial fit-tests. After that, they use a questionnaire, and did not do a fit-test. They use a 3M N95. They have 5800 people, and they've fit-tested 1200 employees per year for the last 5 years. They use a Portacount. S. Eisberg said that 2-3 percent of people report a change on the questionnaire or request a new fit-test. C. Fine said they use a questionnaire, and that employees rarely requested a new fit-test. She supports a face-to-face fit-check. People frequently forget what size they wear. M. Jackson and P. Persaud said that in a fit-check the user demonstrates that they know how to use the respirator.

S. Eisberg said that many people haven't used a respirator since their last fit-test. Training is the most important part. L. Alvarez said that a user seal check is not a substitute for a fit-test. M. Jackson that if there has been an initial fit-test, and a person can do a seal check, and it appears to fit, that should be sufficient. There have been no conversions under those circumstances. L. Alvarez said that the preamble to 1910.134 [federal OSHA's respiratory protection standard] says that in two years a significant number of people change their fit. Her company recommends annual events that combine training and fit-testing. They find that people aren't putting the respirator on correctly when they do the fit-test. Employees should be trained and then fit-tested. M. McDonald said that the training can be achieved by an annual face-to-face fit check. They have an average of 2-6 patients per year with active TB. M. Mendelsohn asked if any studies were being done on this issue.

K. McVay said that you need to consider the human cost of infection, even if the number of people at risk is low. One person at risk is important. This isn't just about money. It is important to do fit-testing. There was an incident in Sacramento where employees were exposed to an infectious disease. Exposures are rare, but they happen. You need to take a drivers test so that you know that you are safe on the road, and you should do the fit-test so that you know you are protected from infection. The institution's first and foremost responsibility is to safety and health, and people's safety should not be negated for money. M. McDonald said that they have 1-2 TB patients per year, and have had no conversions. We make judgments, based on risk. J. Prudhomme said that California is very employer-friendly, but Cal/OSHA regulations do not require a cost-benefit analysis. The issue is how to spend money to provide safety. Employee conversions often can not be directly tied to exposures. M. Nicas said that full protection would require a high level of suspicion, and immediate placement of a suspect case in an airborne isolation room. There are not enough rooms to do that, and it is very costly. There is no basis to change from the annual fit-test requirement unless either we acquire information from federal OSHA that shows that this requirement is wrong, or we acquire new data that shows that no one changes their fit. But if there's no data, this requirement can't be changed. J. Mehring questioned the basis for federal OSHA not requiring an annual fit-test in their proposed TB standard. M. Mendelsohn noted that the hospital industry had opposed the federal TB standard, because they felt there was no need for one. M. McDonald said that follow-up investigations on the 1990 TB guidelines reduced the respirator requirements, and didn't call for annual fit-testing. P. Persaud said that the sole goal is to protect employees, and she's not sure annual fit-testing is doing that. Many exposures come from unknown cases. In the case reported in the Orange County Register, fit-testing wouldn't have helped because the employee didn't think to put on a respirator. She is almost done with annual fit-testing in two hospitals. One is a 200 bed hospital, with 700 employees fit-tested. She isn't sure there is any more protection. M. Jackson said that she suggests fit-testing every three years, and re-testing if there are two or more conversions. B. Nakamura asked what the qualifications should be of a person doing the face-to-face evaluation.

J. Janis said that he had been an RN in an ICU. He got full-blown TB. He doesn't know where he got it, he never met an infection control nurse in the hospital. It doesn't seem like anyone really cares where he got it. It's important to figure out where he got it, or someone else will get TB. M. McDonald said that the CDC guidelines require the institution to investigate PPD conversions and TB cases. B. Nonato said in this case nothing was done. They totally ignored the union's complaints. M. Mendelsohn said that her daughter had been given a two-step test prior to working as a volunteer in a hospital. That fall, she had a 20 mm reaction. She knows what she was doing in the hospital, but it may have been her extra-curricular activities that led to the exposure. The CDC guidelines give good advice regarding care and follow up. J. Janis said that he had gotten good care, but no investigation. P. McCarthy said there may be substantial under-reporting of what's going on. M. McDonald said that in her experience, conversions are reported. C. Fine said that no one is hiding conversions. K. Smith said that this discussion is focusing on TB, but there are other diseases that need to be considered. J. Mehring again asked why federal OSHA didn't require annual fit-testing in their draft TB standard, and M. Nicas replied that they were probably following the CDC recommendations. J. Mehring suggested getting information from the federal TB standard docket, if it is available, on this issue.

Follow-Up

1. Separate meetings will be scheduled for law enforcement and corrections, homeless shelters and other non-hospital environments, and laboratories. There will also be a subgroup to consider an alternative medical questionnaire.
2. Participants are asked to submit data regarding their fit-test experience, as well as data regarding TB conversions and exposure tracing (when conversions are occurring).
3. D. Gold and B. Nakamura will pursue data from the federal docket on annual fit-testing.
4. The next meeting of the full group will be held in the spring. People are asked to e-mail any comments, suggestions, questions or resources to D. Gold or B. Nakamura.